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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,993	07/20/2001	Kazuo Kobayashi	081356/0154	4879

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	17

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,993	KOBAYASHI ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 1 and 9 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 3,4,10-13 and 16 is/are rejected.

7)☒ Claim(s) 2,5-8,14 and 15 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 1-16 are pending in the application.

[2] Applicant's amendment to claims 2-5, 10, and 11 and addition of claim 16 in Paper No. 16, filed June 12, 2003, is acknowledged.

[3] Claims 1 and 9 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[4] Applicant's arguments filed in Paper No. 16 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

[6] Claim 3 is objected to in the recitation of "SEQ ID NO.:2". It is suggested that applicant replace "SEQ ID NO.:2" with the proper sequence identifier "SEQ ID NO:2". See 37 CFR § 1.821(d) regarding sequence identifiers in claims.

[7] In order to avoid confusion, it is suggested that applicant replace "(c)" and "(d)" in claim 3 with "(a)" and "(b)", respectively.

[8] Claims 2-4 are objected to as "endo-β-N-acetylglcosaminidase" is misspelled. It is suggested that "endo-β-N-acetylglcosaminidase" be replaced with "endo-β-N-acetylglucosaminidase".

[9] Claims 5-8, 14, and 15 are objected to as being dependent upon an objected base claim, but otherwise appear to be in a condition for allowance.

Claim Rejections - 35 USC § 112, First Paragraph

[10] The written description rejection of claims 3, 4, 10-13, and 16 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a previous Office action (see item 3 of Paper No. 14). Applicant argues (beginning at the bottom of page 5 of Paper No. 16) the grounds for the instant rejection are inapposite to amended claims 3-4 and 10-13. Applicant argues no undue experimentation would be required for one skilled in the art to practice the described invention because, applicant asserts, one could clearly determine which gene consists of DNA able to hybridize to the prescribed nucleotide sequence under the recited conditions. Applicant's arguments are not found persuasive. It is noted that applicant's argument addresses the scope of enablement rejection under 35 USC 112, first paragraph, and not the instant rejection. Based on the recitation of a hybridization temperature as low as 50 degrees Celsius, the nucleic acids of claim 3 part (d) and claim 4 encompass species that are *widely variant* in structure and the single disclosed species of SEQ ID NO:2 fails to represent the structures of all species encompassed by the genus. The specification fails to describe any additional representative species of the claimed genus. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". As such, the disclosure of the single representative species of SEQ ID NO:2 is insufficient to be representative of the attributes and features of *all* species encompassed by the claimed genus of nucleic acids. Given the lack of description of a representative number of nucleic acids, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[11] The scope of enablement rejection of claims 3, 4, 10-13, and 16 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a previous Office action (see item 4 of Paper No. 14). Applicant argues (beginning at the bottom of page 5 of Paper No. 16) the grounds for the instant rejection are inapposite to amended claims

3-4 and 10-13. Applicant argues no undue experimentation would be required for one skilled in the art to practice the described invention because, applicant asserts, one could clearly determine which gene consists of DNA able to hybridize to the prescribed nucleotide sequence under the recited conditions. Applicant's arguments are not found persuasive. Contrary to applicant's assertion, undue experimentation would be required for a skilled artisan to make the broad scope of claimed nucleic acids, particularly in view of the low hybridization temperatures encompassed by the range of recited temperatures in the claims. A skilled artisan recognizes the inverse relationship of hybridization temperature and the degree of complementarity between a nucleic acid and its complement. Using such low hybridization temperatures as encompassed by the recited range of temperatures, a skilled artisan would recognize the *high* degree of unpredictability that the recited hybridization conditions will allow identification of a gene having sufficient homology such that the gene would encode a polypeptide having endo-β-N-acetylglucosaminidase activity. Thus, in view of the low hybridization temperatures as recited in the claims, an undue amount of experimentation would be required to identify and distinguish those nucleic acids that encode a polypeptide having endo-β-N-acetylglucosaminidase activity from those that do not. While methods of nucleic acid screening by hybridization are well known in the art, screening *all* nucleic acids that hybridize under the recited conditions would clearly constitute undue experimentation.

Thus, it is the examiner's position that the specification has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

[12] Status of the claims:

- Claims 1-16 are pending.
- Claims 1 and 9 are withdrawn from consideration.
- Claims 3, 4, 10-13, and 16 are rejected.
- Claims 2, 5-8, 14, and 15 are objected to.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600